



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAR 11 2005

Mr. Mike O'Connell
Ashbury Biologicals, Inc.
349 Wildcat Road
Toronto, Ontario M3J 2S3
Canada

Dear Mr. O'Connell:

This is in response to your letter of February 16, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Ashbury Biologicals, Inc. is making the following claim, among others, for the product **Hythiol-C**:

"[H]elp the adverse effects of hangover"
"To improve discoloration in skin pigmentation due to...eczema, urticaria,
rash...sunburn."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases, such as the consequences of alcohol poisoning/overdose (i.e., hangover) and dermal manifestations of various diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

975 0153 LET 814

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal line extending to the right.

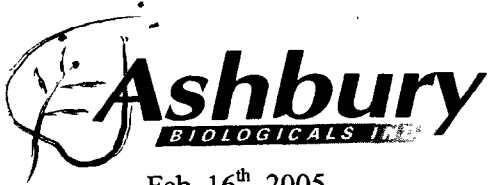
Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New York District Office, Office of Compliance, HFR-NE140



Feb. 16th, 2005

Office of Special Nutritionals (HFS-810)
Center for Food and Safety and Applied Nutrition Food and Drug Administration
5100 Point Branch Parkway
College Park, Maryland
20740

Re: Statements of Nutritional Support for the following product:

FEB 22

1) Hythiol-C

Dear Sir:

Ashbury would like to notify the Food and Drug Administration that it has commenced marketing the dietary supplement Hythiol-C in the USA within the past 30 days.

Please consider the following as notification of Statements of Nutritional Support as required by Section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with Section 101.93 of 21 Code of Federal Regulations.

Distributor Name & Address: Ashbury Biologicals Inc.
349 Wildcat Road
Toronto, Ontario
M3J 2S3

Statement Text:

To eliminate alcohol from the body and help the adverse effects of hangover.
For general weariness and physical well being.
To improve skin condition and reduce skin eruptions for better complexion
To help lighten and fade away brown spots generally caused by aging.
To help lighten and fade away brown spots caused by the aging effects of the sun
To improve discoloration in skin pigmentation due to pimples, eczema, urticaria, rash, chloasma, melasma, freckles and sunburn.

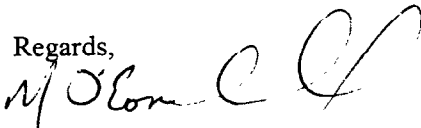
Dietary Ingredients:

L-Cysteine
Vitamin C
Calcium Pantothenate

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.

Can you please confirm receipt of this notification by e-mail to ashbury@dalton.com.

Regards,


Mike O'Connell

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